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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/777,790	02/11/2004	Jacqueline C. Timans	DX01040K3B	3044

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DNAX RESEARCH INC.
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EXAMINER	
JIANG, DONG	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
01/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/777,790	TIMANS ET AL.	
	Examiner	Art Unit	
	Dong Jiang	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,26-33,37,38 and 40-57* is/are pending in the application.

4a) Of the above claim(s) *41-50* is/are withdrawn from consideration.

5)☒ Claim(s) *32 and 53* is/are allowed.

6)☒ Claim(s) *16, 26-31, 33, 37, 38, 40, 51, 52 and 54-57* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *16,26-33,37,38 and 40-57* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

The request filed on 25 October 2007 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 10/777,790 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 25 October 2007 is acknowledged and entered. Following the amendment, claims 16, 26-32, 38, 40, 41 and 44-50 are amended.

Currently, claims 16, 26-33, 37, 38 and 40-57 are pending, and claims 16, 26-33, 37, 38, 40 and 51-57 are under consideration.

New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 52 and 54 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the last Office Actions mailed on 8/21/07, on page 3.

Applicants argument filed on 25 October 2007 has been fully considered, but is not deemed persuasive for reasons below.

At pages 9-10 of the response, the applicant argues that the specification is amended herein to recite "covalent or aggregate conjugates with other chemical moieties, e.g., PEGylation", and such an amendment is proper under 37 C.F.R. § 1.57(f), that the specification cites three different texts including the Lundblad and Noyes (1988) reference, which provide background techniques for preparing covalent derivatives including PEGylated derivatives, and

are incorporated by reference in their entirety, that PEGylation is a very well known technique, and those of skill in the art are readily aware PEGylation technique, and that PEGylation is adequately identified by the present specification and the Lundblad and Noyes (1988) disclosure of PEGylation provides support for the amendment to the specification. This argument is not persuasive because, as addressed in the last Office Action, the cited reference teaches various techniques for protein modifications, and MPEP requires that particular attention should be directed to specific portions of the referenced document where the subject matter being incorporated may be found (608.01(p), I. A.). The issue is not whether those of skill in the art are aware of PEGylation technique, rather, the issue is that sufficient particularity is required when incorporating by reference.

This is a new matter rejection.

Rejections under 35 U.S.C. 112:

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 26-31, 33, 37, 38, 40, 51, 52 and 55-57 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited in scope to an isolated polypeptide of SEQ ID NO:2 capable of binding to the receptor of SEQ ID NO:12, does not reasonably provide enablement for claims to an isolated polypeptide *comprising* at least 17, 20, 25, 30, 35, 50 or 75 amino acids of SEQ ID NO:2 (claims 16, 26-31 and 40, for example), or % variants of SEQ ID NO:2 (claims 38 and 39, for example), binding to any or all cell surface receptors. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the previous Office Actions mailed on 2/6/07 and 8/21/07.

Applicants argument filed on 25 October 2007 has been fully considered, but is not deemed persuasive for reasons below.

At page 11 of the response, the applicant argues that the test for enablement is whether experimentation alleged to be necessary is undue, not whether any experimentation is necessary, and when the art typically engages in a type of experimentation, that experimentation is not considered undue (*In re Wands*), that in this case, one of skill in the art would merely need to perform a competitive binding assay to see if the selected polypeptide fragments or variants compete with the full length polypeptide of SEQ ID NO:2 in binding to WSX-1/TCCR, and it is easily within the skill of a skilled artisan to generate and identify the claimed polypeptides without undue experimentation. This argument is not persuasive for the following reasons. First, the specification does not teach the structural and functional relationship of the polypeptide of SEQ ID NO:2, and the claims encompass fragments as small as 17 or 20 amino acids (for example), thus, in order to make the functional fragments and variants that commensurate in scope with the claims, *the large quantity of experimentation* to generate the infinite number of fragments and variants recited in the claims and possibly screen same for activity would be necessary, which does constitute undue burden (see "Wands factors", *In re Wands*), even though the experimentation itself is routine. Further, given the fact that the polypeptide of SEQ ID NO:2 is only a part of a molecular complex (of IL-27, which is comprised two polypeptides), and that the polypeptide of SEQ ID NO:2 is 242 amino acids in length, a fragment of 17 amino acids is unlikely to possess the desired functional property. The specification provides neither the structural and functional relationship of the polypeptide, nor any guidance/working example of the fragment or variant meeting the limitation of the claims. Therefore, undue experimentation would be required of the skilled artisan to make and use the claimed invention in its full scope.

Claims 16, 26-31, 33, 37, 38, 40, 51, 52 and 55-57 remain further rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the previous Office Actions mailed on 2/6/07 and 8/21/07.

Applicants argument filed on 25 October 2007 has been fully considered, but is not deemed persuasive for reasons below.

At pages 11-14 of the response, the applicant argues that MPEP § 2163.02 states that "[t]he subject matter of the claim need not be described literally in order for the disclosure to satisfy the description requirement", and the Applicants have provided sufficient information in the specification such as the sequence, structure (helixes) and functional property (IL-27 binds to WSX-1/TCCR) of the polypeptide of SEQ ID NO:2, and that Example 14 of the Guidelines only indicates 95% identity is patentable, but there is no limitation in the Guidelines, MPEP, or case law that finds this example to be an absolute limit. This argument is not persuasive because although the specification discloses the sequence, helixes and functional property of the polypeptide of SEQ ID NO:2, it does not provide the correlation between sequence structure and functional activity for the polypeptide. Further, although there is no limitation in the Guidelines, MPEP, or case law that finds Example 14 to be an absolute limit, given the limited information disclosed in the instant specification regarding a new molecule, i.e., there is no the correlation between sequence structure and functional activity disclosed for the polypeptide of SEQ ID NO:2, and there is guidance/working examples given to make the variants thereof with the desired functional property, a skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide variants, and would not recognize from the disclosure that applicants was in possession of the claimed genus with a broader scope (90%). Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of making it.

Conclusion:

Claims 32 and 53 are allowable.

Advisory Information:

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol, can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Dong Jiang, Ph.D.
Patent Examiner
AU1646
1/16/08